KENX
KNOWLEDGE EXCHANGE NETWORK

GMP University Presents 3 Concurrent Events:

Internal Audits and FDA Inspections
Quality Risk Management (QRM)
Change Control

August 21-23, 2018 | The Doubletree Hotel Center City | Philadelphia, PA

KEYNOTE PRESENTATION AND FEATURED PRESENTER

Regulatory Intelligence – Staying Up-to-Speed on Regulatory Thinking

Karyn M. Campbell

Director, Investigations Branch II, Division of Pharmaceutical Quality Operations

U.S. Food and Drug Administration (FDA)

AUDITS & INSPECTIONS

- Build a Sustainable Program that Boosts Compliance & Increases Value
- Discover the Benefits of Risk-Based Planning & Auditing
- Develop a Comprehensive Data Integrity Audit Plan
- Learn How to Write Successful Response
- Participate in a Mock Audit & Sharpen Your Skills

RISK MANAGEMENT

- Develop Ranking Criteria & Action Tables
- Integrate Custom Risk Tools into Your Quality Systems
- Bias and Heuristics and in the Risk Management Process – Understand the Human Factor
- Discover the Importance of Decision Maker Roles & Responsibilities
- Successful FMEA Training: Play with a Purpose

CHANGE CONTROL

- Categorize and Determine the Level of Changes
- Identify Potential Risks & Impact to Product Quality
- Apply Risk Management in Change Control
- Discover the Benefits of Planning for Software Upgrades
- Present your Change Control Program to an Inspector

ELITE FACULTY INCLUDE

Merck – **Mary Farbman,** Executive Director, Compliance Remediation and Support

Abbott Laboratories – **Erik Muegge,** M.S., Manager Operations Quality

Merck – **Ghada Haddad,** Executive Director, Global cGMP and Auditing Organization

Sanofi – **Jon Williams** Quality Risk Management

Shire plc – **Joseph Zec** Associate Director, CSV and Compliance

And Many More

ADVISORY COMMITTEE AND PROGRAM CO-CHAIRS

Mony Clark,
Senior Compliance Specialist and Lead Auditor,
Bayer Pharmaceuticals

Kelly Waldron,
Senior Consultant, ValSource; &, Member, Pharmaceutical Regulatory Science Team (PRST),
Dublin Institute of Technology

REGISTER BEFORE JULY 20TH AND **SAVE $300**

Day One – August 21, 2018

12:00 Conference Registration
Coffee and Lite Snacks On-the-Go

1:15 Co -Chair and Advisory Committee Opening Remarks

Mony Clark, Senior Compliance Specialist and Lead Auditor, **Bayer Pharmaceuticals**

Kelly Waldron, Senior Consultant, **ValSource**; and, Member, Pharmaceutical Regulatory Science Team (PRST), **Dublin Institute of Technology**

Keynote Session and Featured Speaker

1:30 Regulatory Intelligence – Staying Up-to-Speed on Regulatory Thinking

Karyn M. Campbell, Director, Investigations Branch II, Division of Pharmaceutical Quality Operations, **U.S. Food and Drug Administration (FDA)**

- What's new at FDA?
- Hot topics for regulatory inspections – Data integrity, change control and risk management
- What are FDA's expectations during an investigation
- Uncover 5 top challenges FDA is observing – A Philadelphia District perspective
- Discover best practices investigators see

2:15 Staying Compliant by Knowing & Understanding Warning Letter Trends

Erik Muegge, M.S., Manager Operations Quality, **Abbott Laboratories – Diagnostics Division**

The "c" in cGXP is "current". To stay up to date with current industry practice and regulatory expectations, a reliable source is knowing and understanding current trends in Warning Letters. This session discusses:

- Understanding the purpose of the Warning Letter
- Warning Letters give you part of the picture – How to leverage this for your programs
- Current Warning Letter analysis and trends
- Based on the trends, key items to consider as you evaluate your compliance program

3:00 Afternoon Refreshment Break

3:30 WHO GMP Global Inspection Readiness

Kim Huynh-Ba, Executive Director, **Pharmalytik**

- Understand Principles of Quality Management System that support Good Manufacturing Practices (GMP)
- Discuss World Health Organization (WHO) expectations of a GMP inspection process
- Discuss requirements for documentation and records
- Determine critical issues via risk management concepts
- Maintain compliance and efficiency throughout product lifecycle

4:15 ICH Guidance and Why You Should Care

Gamal Amer, Ph.D., Principal, **Premier Compliance Services, Inc.**

A high-level review of ICH quality guidance and their requirements. This presentation reviews the five finalized ICH Guidance and highlight their most important requirements and the impact on your compliance efforts.

- ICH Q7 GMP Guidance for API
- ICH Q8 Pharmaceutical Development
- ICH Q9 Quality Risk Management
- ICH Q10 Pharmaceutical Quality System
- ICH Q11 Development and Manufacture of Drug Substances
- Proposed ICH Q12 Technical and Regulatory Considerations for Pharmaceutical Products Lifecycle Management

5:00 Scholarship Award and Welcome Reception

TEMPLE UNIVERSITY
School of Pharmacy

School of Pharmacy
TEMPLE UNIVERSITY
Regulatory Affairs and Quality Assurance Graduate Program of Temple University School of Pharmacy

Day Two – August 22, 2018

7:00 Coffee and Lite Breakfast

7:30 – 8:15 Select Between Knowledge Exchange Sessions (1-3)

1 | Auditing Contract Manufacturing Organizations (CMOs)

Loren Kim, Principal Quality Systems Consultants, **QSI Consulting, LLC**

- Overcome challenges to auditing CMOs
- CMO communication and cooperation: Develop & plan audits
- Develop an audit plan by determining the critical to quality parameters
- Understand the CMOs process flow and turnaround time for gating activities
- Assess bandwidth and available resources

2 | ICHQ9 – A Foundation and Resource for Success

Jon Williams, Quality Risk Management, **Sanofi**

- Focus on the patient
- The QRM lifecycle
- QRM as a process to make informed decisions
- Annex 1 – Method and Tools
- Annex II – Potential Applications for QRM

3 | Introduction to Change Control Regulation: What's Required

Alan Golden, MS, Principal Quality Professional, Product Quality Operations Support, **Abbott Molecular**

- Change control regulations overview
- Change control regulations and guidance
  - FDA
    - 21CFR820, Quality System Regulations
    - 21CFR211, Current Good Manufacturing Practice for Finished Pharmaceuticals
    - Guidance for Industry Quality Systems Approach to Pharmaceutical CGMP Regulations
  - ISO 13485
  - ICH Q10
- Summary of what is required for effective change management

8:30 – 12:00 Select Between Knowledge Exchange Workshops (A-C)

A | Bio/Pharmaceutical Audit Management Boot Camp

Mony Clark, Senior Specialist, QA Site Compliance, **Bayer Pharmaceuticals**

Part 1 – Audit Management Success Plan

- The evolution of auditing: Where it started & where it is headed
- What is a successful audit?
- The 4 roles of the lead auditor: audit manager, project manager, auditor, consultant
- Learn the language of upper management & understand the bottom line
- Four key steps for successful audit management
- Audit planning and developing the audit strategy
- Traditional audit planning and risk-based audit planning
- Audit execution and fieldwork
- Manage the audit and the audit team
- Best Practices (Audit) Handbook
- Audit reporting and review: Demonstrate the value & relevance
- Corrective Action and Preventive Action: Take the holistic approach
- Establish the communication and escalation process
- Measure the effectiveness of the audit

Part 2 – Advanced Auditing: More than a Profession, It's a Skill

- Master the six skills to become a successful auditor
- Know the regulations: Understand the application of regulations and standards
- Communication skills and staging the interview
- Conflict management 101
- Leverage and influencing your peers and stakeholders
- Lean tools and lean auditing
- Risk-Based Quality Auditing (RBQA)
- Classification of findings by risk
- Audit checklist development matrix
- Root Cause Analysis (RCA) tools
- Data and trend analysis: How to analyze data effectively

Knowledge Exchange

Attendees take part in a virtual room escape to test comprehension and knowledge of audit management, discuss challenges and issues, and strategize on solutions and best practices. Attendees also take part in a "Sherlock Holmes" investigation to put their auditing techniques and skills to the test.

Takeaway Tools ⚒

- Examples of lean tools
- Template for audit checklist development matrix
- Template for a risk-based audit planning calculation model
- Example of finding classification by risk

B | The Most Under-Utilized QRM Tool in Industry

Amanda B. McFarland, Senior Consultant, **ValSource, LLC**

Part I – Risk Tools vs. A Custom Risk Tool

- Explore Common Risk Tools
  - Overview of commonly executed risk management tools and what we can learn from them
  - Evaluate parameters frequently measured to determine risk
- Understand When a Custom Risk Tool is Appropriate
  - Explore the reasons for developing a custom risk tool
  - Explain the intent of a custom risk tool
  - Describe when a custom risk tool is & is not appropriate
  - Outline opportunities for creating custom risk tools
- Less-Formal Risk Tool Approaches
  - Explain the format options for developing a custom risk tool
  - Understand the difference between the checklist, decision tree and Risk Estimation Matrix (9-box)
  - Provide examples of custom risk tools & their application

Part II – Into Action – Develop a Custom Risk Tool

- Define the "What"
  - Learn the elements to consider when developing a risk tool
  - Determine what to measure with a custom tool
  - Identify how to organize a risk tool & determining the order of operations
- Develop Ranking Criteria and Action Tables for a Custom Risk Tool
  - Outline the characteristics of robust ranking criteria
  - Identify how to develop ranking criteria for custom risk tools
  - Learn to create action tables which link back to the intent of the tool
- Implement a Custom Risk Tool
  - Describe strategies for evaluating the robustness of a custom tool
  - Outline how to integrate custom risk tools into your quality systems
  - Selling a custom tool to leadership

Knowledge Exchange

During this session, participants use the principles from the class to create a framework for a custom risk tool.

Takeaway Tools

- Examples of less formal risk tool formats
- Understand how to identify the parameters to be measured using a custom risk tool
- Strategy for developing sound risk-ranking criteria

C | Build and Maintain an Inspection-Ready Change Control Program

Kim Huynh-Ba, Executive Director, **Pharmalytik Consulting**

Part 1 – Establish an Effective Change Control Process

- Structure of a change control process
- Manage changes to current process or product
- Categorize and determine the level of changes
- Identify potential risks and impact to the product quality

Part 2 – Build and Maintain the Change Control Program for Inspection

- Understand the sequences of an inspection
- Establish good record keeping for GMP & non-GMP studies
- Determine and trend critical quality attributes
- Establish a process of handling inspections
- Understand Quality Management System to minimize the impact of Warning letters

Knowledge Exchange

Attendees take part in a group discussion of strategies to manage the change control program to minimizing the potential risks.

Takeaway Tools

- General flow and critical input for change control process
- Example of distinct types of changes that can impact product quality. Prepare the change
- Prepare the change control program for inspection

12:00 Lunch and Learn Sessions (4-6)

4 | Common Audit Challenges

Erik Muegge, M.S., Manager Operations Quality, **Abbott Laboratories – Diagnostics Division**

- Discuss common challenges/issues for several types of audits
- Establish common ground and benchmark
- Understand challenges and see how others may have addressed them
- Share best practices to benefit others

5 | Pitfalls in Quality Risk Management – Top Ten Most Common Errors

Kelly Waldron, Senior Consultant, **Valsource** and Regulatory Science Researcher, **Dublin Institute of Technology**

- Uncover the top ten most common errors in QRM
- Avoid vulnerability in an inspection
- Discover the value you can derive from the effort
- Become aware of mistakes you may be making that could derail your QRM efforts

6 | The Five Most Important Challenges Faced in Implementing Change Control

Gamal Amer, Ph.D., Principal,
Premier Compliance Services, Inc.

- Deal with emergency changes
- Apply risk management in change control
- Post change monitoring and its importance
- The need to revalidate because of change
- Is a change control committee always needed to address changes?

1:15 – 2:45 Select Between Knowledge Exchange Sessions (7-9)

7 | Internal Audit Programs – Boost Compliance & Increase Value to the Organization

Mony Clark, Senior Specialist, QA Site Compliance,
Bayer Pharmaceuticals

Part 1 – Build a Sustainable and Effective Internal Audit Program

- Importance of the internal audit program: Meeting regulatory requirements, driver for continuous quality and business improvement, and managing risks
- Examples of Warning Letters
- The "three-legged stool" of a robust Audit program
- The role of the audit program manager and lead auditor
- Building the audit team and identifying clear roles and responsibilities
- Build, train, develop, and maintain qualified auditors
- In-house versus external auditors
- Influence stakeholders and overcome the "boss" barrier
- Auditing for risk: Integration of risk management into the audit program
- The auditee response: Have an effective Root Cause Analysis (RCA) program
- Establishing the communication and escalation process
- Measuring the effectiveness of the Internal Audit program
- Transforming the quality and compliance culture

Part 2 – The Benefits of Risk-Based Audit Planning and Auditing

- Is risk-based audit planning the right approach for every circumstance?
- In-depth: Integrate risk management into the audit program
- Review of a risk-based calculation model for Audit Planning
- Know when to adjusting the audit schedule
- Risk-Based Quality Auditing (RBQA)
- Classification of findings by risk
- Decision mapping for risk identification and response process flow

Takeaway Tools

- Example of risk identification and response process flow
- Example of finding classification by risk
- Template of risk-based calculation model for audit planning

8 | QRM Master Class - Ask the Expert

Kelly Waldron, Senior Consultant, **Valsource** and Regulatory Science Researcher,
Dublin Institute of Technology

Part 1 – Solutions to Common Challenges

- Learn expert-vetted solutions to the top ten most common challenges in QRM (discussed in the Lunch & Learn "Pitfalls in Quality Risk Management – Top Ten Most Common Errors")

Part 2 – Knowledge Exchange

- Find answers to your most pressing questions. Ask the speaker anything, from current regulatory expectations, what to do in specific QRM situations, & what not to do based on challenges others have faced.

9 | Change Control for Computer Systems: Software Upgrades

Chinmoy Roy, Data Integrity and CSV SME, Consultant

Part 1 – The Benefits of Planning for Software Upgrades

- Understand the difference between version, update & upgrade
- Understand the considerations and triggers for upgrade and update
- What is the role of computerized system controls in software upgrades
- What is the role of configuration management
- Familiarize yourself with the regulatory requirements for software updates and updates
- Understand why the Lifecycle approach is critical for software upgrades of medical devices

Part 2 – Implement and Deploy Software upgrades

- Perform a risk analysis for the Upgrade
- Build a team to implement upgrade using lifecycle approach
- Testing and validation of software upgrades: why is it somewhat different
- Overcome the unique challenges in the deployment of software patches and upgrades

Takeaway Tools

- Typical SOP for software upgrades and configuration management

2:45 Afternoon Refreshment Break

3:15 – 4:45 Select Between Knowledge Exchange Sessions (10-12)

10 | So, You're Not Auditing Data Integrity Yet (But You Should Be)

Chinmoy Roy, Data Integrity and CSV SME, Consultant

Part 1 – Develop a Data Integrity Audit Ian

- Understand data integrity dimensions
- Become familiar with regulatory agencies' data integrity audit trends
- Explore what regulatory agencies look for during data integrity audits
- What factors to consider during your planning for internal audits of DI
- Understand how to monitor the state of data integrity health after your internal audit
- Understand management's role in the success of DI internal audits
- Discover how DI audits for vendors differs from internal audits

Part 2 – Implement the Data Integrity Audit Plan

- What to look for during your audit walk through
- Develop a checklist prior to your data integrity audit
- Interview tactics for unraveling potential data integrity problem areas
- Use critical thinking skills during your audit
- Use the data integrity maturity model in your final report

Takeaway Tools

- Typical SOP for DI internal audit

11 | QRM Open Forum: Benchmark with Your Peers

Kelly Waldron, Senior Consultant, Valsource and Pharmaceutical Regulatory Science Researcher, **Dublin Institute of Technology**

This session entails a facilitated discussion of QRM best practices and solutions to challenges. Attendees are asked to submit their questions in advance and can learn how their peers in industry approach Quality Risk Management to maximize value and compliance. Topics may include risk tools, techniques, requirements to perform risk assessments or use risk-based approaches, and cultural constraints such as resource limitations and reactive "fire-fighting" mindsets.

** This session also addresses aspects of the originally scheduled session on Bias and Heuristics and in the Risk Management Process.

12 | Creating Change Plans for Change Control: What Works and What Doesn't

Alan Golden, MS, Principal Quality Professional, Product Quality Operations Support, **Abbott Molecular**

Part 1 – Drivers and Need for Change

- External and internal change drivers
- Business needs and regulatory requirements
- Regulatory Requirements
- Change, Reason, and Justification
- Impact Assessment

Part 2 – Setting Up a System for Change Control that Works

- Conducting an impact assessment and understanding the importance
- Planning for change
  - What works
  - What does not work
- Integrating risk assessments into change control

Knowledge Exchange

Attendees participate in a think tank and discuss their change control experiences and has worked and what has not.

4:45 Close of Day Two

Day Three – August 23, 2018

7:00 Coffee and Lite Breakfast

7:30 – 8:15 Select Between Knowledge Exchange Breakfasts (13,15)

13 | Inspection Readiness–How to Ensure You're Ready for Your Next Health Authority Inspection

Mary Farbman, Executive Director, Compliance Remediation and Support, **Merck**

- Design an inspection readiness plan
- Audits vs. mock inspections vs. inspection readiness coaching: Which model is best for you?
- Challenge your response to unannounced inspections
- Set up an efficient and effective backroom
- Learn how to train your SMEs on appropriate inspection behaviors
- Determine which topics need guiding presentations in advance of your inspection and how to develop those presentations

15 | Handling Automatic Software Upgrades in Cloud Systems (XaaS)

Chinmoy Roy, Data Integrity and CSV SME, **Consultant**

- Cloud management models and GxP considerations
- GxP risks associated with cloud services
- What do we qualify and what do we Validate for cloud services
- Maintaining the validated state of cloud services
- Release and deployment management for cloud software upgrades

8:30 – 12:00 Select Between Knowledge Exchange Workshops (D-E)

D | What Would You Do: Inspection Preparation Think Tank

David W. Vincent, Ph.D., CEO, **VTI Life Sciences**

Part 1 – How to Manage Your Team During the Inspection

- Set up the war room – Back room, SME preparation, on deck and inspection room
- Organizing for bundled inspection topics
- How to organize staff to speak with the inspector(s)
- Mentor junior staff in the inspection process (trial by fire)
- Understand what is important in the inspection
- Manage the chaos of unexpected events
- Typical validation inspection topics (sterilization practices (autoclave), cleaning practices (automated and manual), environmental monitoring, controlled temperature units (freezers, fridges, walk-ins) and requalification

Part 2 – What Would You Do? Managing Inspections Gone Wrong

- Prepare for an inspection with a weak legacy program
- Manage the inspection experience when documentation is unsatisfactory
- Manage the presentation when the discussion goes poorly
- Handle the bad news at the inspection
- Create a robust response
- Transition plans

Knowledge Exchange – Recognize and Respond to Adverse Conditions

Attendees participate in a mock inspection and set up a mock audit room (with auditor, QA host, scribe, participants, etc.) and run through several scenarios, starting with small issues and larger issues that may lead into a patient safety/recall category.

E | Prepare for a QRM-Focused Inspection

Ghada Haddad- Executive Director, Global cGMP and Auditing Organization, **Merck**

Darshana Patel, Associate Director Quality Risk Management Center of Excellence, **Merck**

Part 1 – 13 years after ICHQ9, where is QRM Today?

- Are the full benefits of QRM as a valuable component within a pharmaceutical quality system realized?
- Challenges with applying QRM principles and experience with presenting QRM documents to regulators

Part 2 – Regulatory Inspections of QRM

- List of QRM inspection observation from various regulatory agencies
- Inspection preparation
- Presenting to health authorities
- Potential pitfalls
- How to leverage internal audits
- Tips for surviving an inspection focused on QRM review

Knowledge Exchange

Attendees take part in a round-the-room review of QRM application examples and identify potential issues and on the industry needs to ensure QRM's intent is realized

F | Presenting Your Change Control Program to an Inspector

Joseph Zec, Associate Director, CSV and Compliance, **Shire plc**

This session helps attendees put a strategy in place for shining the best light possible on your change control program during an inspection.

Part 1 – Preparing

- Catalog policy and procedural documentation
  - Perform a QC check
- Gather evidence
  - Change control records
  - Supporting documentation
    - Assessments
    - Test results
- Assess validation status of change control computerized system
- Identify and prepare personnel
  - Front room
  - Back room
- Prepare a storyboard
- Perform a dry run

Part 2 – Presenting

- Work down from policy level
- Show how company process supports regulatory requirements
- Really emphasize the "control" part of the process
- Walk through example change controls
  - Golden example
  - Tin example
- Show how automation regulates workflow and approvals
- Discuss the future direction of change control at your company

Knowledge Exchange – Spot the Red Flags!

Attendees work in breakout teams to analyze various inspection scenarios, identify potential red flags, and strategize ways to lessen their impact.

10:00 Mid-Morning Refreshment Break

12:00 Lunch and Learn Sessions (16-18)

16 | Transition from Compliance Police to Compliance Partner

Loren Kim, Principal Quality Systems Consultants, **QSI Consulting, LLC**

- Bridge communication and cooperation between quality and operational groups
- Discuss challenges in breaking established culture/stereotypes of QA vs. Manufacturing
- Learn How to approach QMS development across the organization
- Incorporate best practices and share information between organizational groups
- Work with operational groups and incorporate compliance "goals" as a part of personal & organizational performance metrics

17 | A Case Study Journey towards a Robust QRM Program

David W. Vincent, Ph.D., CEO, **VTI Life Sciences**

- Overview of one companies risk management implementation process
- Discuss how to get started
- Incorporate risk management into your company philosophy
- Share risk processes that have worked (and haven't)

18 | Post Approval Change Control Protocols

To Be Announced

- FDA and global regulations
- What is it and what goes into the protocol
- Describe specific changes to implement during the lifecycle of the product
- Conduct a risk assessment of the impact of the change on product quality

1:15 – 2:45 Select Between Knowledge Exchange Sessions (19-21)

19 | FDA "Live Review" Inspections

Camilla Perrotta-Fowler, cGMP Compliance Training Sr. Specialist, **Bayer Healthcare**

Part 1 – Traditional Inspections versus "Live Review"

- The evolution of inspections: How it used to be and where it is headed
- Understand the difference between traditional inspections versus "live review"
- Review examples of evidence of "live review" in published Warning Letters and the outcomes
- Review examples of new data requests compared to traditional documentation requests
- How to overcome challenges to hosting a "live review"

Part 2 – Successful Planning for "Live Review"

- Case study of FDA "live review" inspections
- Based on the trends, key items to consider as you evaluate your inspection readiness program
- Adapting to the new approach (e.g. quality documentation, putting your data and computer systems to the test)
- How to prepare SMEs and 'pressure test' preparedness
- Modern day inspection back room management

Knowledge Exchange

Attendees conduct a live "mock inspection" session and work together to develop and share best practices to the "live review" approach in action.

Tangible Takeaways

- Examples of "live review" in action
- Template for "mock inspection" simulations
- Techniques for "live review' preparation

20 | Successful FMEA Training: Play with a Purpose

Jon Williams, Quality Risk Management, **Sanofi**

Part 1 – Learning through Illumination

- Set the stage for training success
- Props: Let's get visual
- Create active participation opportunities
- Balance technical vs. non-technical examples
- Increase peer positivity and team cooperation

Part 2 – Grow in Risk Maturity

- Answer complex risk questions through strategy simulation
- Move from fixed to growth mindset
- QRM lifecycle: Opportunity for improvement

Knowledge Exchange

Are we training for successful FMEA assessments? Attendees participate in one training exercise, share best practices and leave with innovative ideas on FMEA training strategy.

Takeaway Tools

- FMEA training tools
- Training strategies for continued risk maturity
- Understanding how risk training differs from other quality systems

21 | Implementing a Global Change Control Process – A Case Study

Joseph Zec, Associate Director, CSV and Compliance, **Shire plc**

This case study examines how one multi-national company consolidated a fractured landscape of local change control processes and computerized systems into a single harmonized methodology.

Part 1 – Out with the old…

- Identifying legacy procedures
- Transition Planning
- Retiring legacy procedures
  - Breaking old habits
- Retiring legacy change control systems
  - What to do with all that legacy data?

Part 2 – …And in with the new

- Identifying stakeholders
- Unifying to a single process
  - The importance of corporate standards
  - Roles and responsibilities
  - Reaching consensus
- Unifying to a single application
  - Which comes first, the process or the system?
  - Ingredients for a successful implementation

Knowledge Exchange – Let's Go Global!

Attendees work in breakout teams to solve global change control challenges.

2:45 Afternoon Refreshment Break

3:15–4:45 Select Between Knowledge Exchange Sessions (22-24)

22 | Observations and Responses – Interpret and Respond to Regulatory Concerns

Mary Farbman, Executive Director, Compliance Remediation and Support, **Merck**

Part 1 – Successful Response Writing Strategies

- Understand what agencies are looking for in a response
- Review examples of poor responses: What went wrong and why?
- How, why and when to generate a response calendar
- Day 1: Response strategy sessions
- Tips on authoring and reviewing responses
- Significance of the introductory statement
- How to respond if you don't agree with the observation
- Use of risk assessments in responses

Part 2 – We've Responded: Now What?

- Ensure appropriate ownership of CAPAs
- Tools for CAPA tracking and completion
- Generation of CAPAs not specifically referenced in responses
- Using regulatory concerns to make holistic improvements in your quality system
- Auditing your regulatory commitments
- Preparing for discussions of CAPAs at the next inspection

Knowledge Exchange: Case Study

In groups, attendees prepare a plan for responding to a lengthy Form FDA-483

Takeaway Tools

- Example of a response calendar
- Templates for response strategy sessions

23 | Implement Risk Management in the Change Control Processes

Gamal Amer, Ph.D., Principal, **Premier Compliance Services, Inc.**

Part 1 – Understand the Importance of Change Control

- The need for change
- Where do changes occur
- Change control and maintaining the state of control

Part 2 – Understand the Risks Associated with Implementing the Change Control Procedure

- Risk of process failure
- Compliance risk
- Risk to product quality
- Risk to the patients and the public

Part 3 – Managing the Risks Associated with the Change Control

- Understand the level of risk
- Manage the risk based on the level
- Review and measure your success
- Apply the proper quality metrics

4:45 Close of Conference

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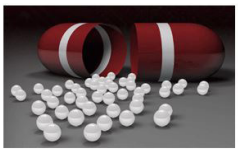

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